



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/808,878 03/15/01 PICKAR

J AM100226

EXAMINER

HM12/0913

EGON E. BERG
AMERICAN HOME PRODUCTS CORPORATION
PATENT LAW DEPARTMENT
FIVE GIRALDA FARMS
MADISON NJ 07940

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/808,878

Applicant(s)

PICKAR, JAMES H.

Examiner

Mojdeh Bahar

Art Unit

1617

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 15-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a method of treating or inhibiting menopausal or postmenopausal disorders, classified in class 514, subclass 178.
- II. Claims 7-14, drawn to a method of treating or inhibiting vasomotor symptoms classified in class 514, subclass 178.
- III. Claims 15-19, drawn to a method of inhibiting or retarding bone demineralization, classified in class 514, subclass 178.
- IV. Claims 20-24, drawn to a method of treating vaginal atrophy, classified in class 514, subclass 178.
- V. Claims 27-31, drawn to a method of treating cardiovascular disease, classified in class 514, subclass 178.
- VI. Claims 32-36, drawn to a method of treating or inhibiting free radical movement, classified in class 514, subclass 178.
- VII. Claims 37-41, drawn to a method of treating dementia, classified in class 514, subclass 178.
- VIII. Claims 42-50 and 67-68, drawn to a pharmaceutical composition, classified in class 514, subclass 178.
- IX. Claims 51-55, drawn to a method of decreasing breast pain, classified in class 514, subclass 178.
- X. Claims 56-61, drawn to a method of decreasing spotting, classified in class 514, subclass 178.

XI. Claims 62-66, drawn to a method of increasing bone mineral density, classified in class 514, subclass 178.

The inventions are distinct, each from the other because of the following reasons:

Inventions VIII and I-VII, IX-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of treating cardiovascular disease and its underlying conditions including atherosclerosis and hypercholesterolemia can be practiced with another materially different product such as pravastatin, Angiotensin Converting Enzyme inhibitors, e.g., captopril and enalapril. Bone demineralization can be treated by calcium supplements, breast pain can be treated by using analgesics, for example.

Inventions I-VII and IX-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions have different functions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Specie Election

Claims 1-14, 20-24, 27-41 are generic to a plurality of different disclosed patentably distinct disorders. Applicant is required under 35 U.S.C. 121 to elect a single

Art Unit: 1617

disclosed species, even though this requirement is traversed. The treatment of each represents a separate field of medical technology having a separate field of search. The search for treatment of all menopausal and postmenopausal disorders is therefore an undue burden on the office.

Note that the search is not limited to patent files.

During a telephone conversation with Arnold S. Milowsky on August 27, 2001, a provisional election was made with traverse to prosecute the invention of Group II, claims 7-14 and hot flushes as the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6 and 15-68 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 7-14 are examined on the merits in so far as they read on the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plunkett et al. (USPN 4,826,831, RE 36,247)

Plunkett et al. (USPN 4,826,831) teaches a method of treating hot flushes comprising administering continuously and uninterruptedly both progestogen and estrogen in daily dosage units, see claim 1 and col.9 lines 34-40 in particular. Plunkett et al. (USPN 4,826,831) also teaches conjugated equine estrogen/medroxyprogesterone as one of the estrogen/progestogen combinations useful in its method, see claims 3, 5 and 8. Plunkett teaches the minimum and

Art Unit: 1617

maximum dosages for medroxyprogesterone to be 1 mg/day and 15 mg/day respectively, see claim 4 in particular. Plunkett teaches the dosage range for Ethinyl estradiol to be between 0.005 and 0.020 mg/day, and the dosage range of quinestranol to be between 0.005 and 0.020 mg/day, see claim 5.

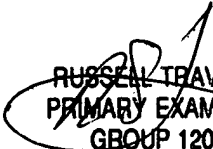
One of ordinary skill in the art would have been motivated to employ any of the estrogen/progestogen combinations taught in Plunkett in a method of treating hot flushes because they are known to be useful in methods of treating menopausal disorders including hot flushes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 7, 2001


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200